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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,947	12/22/2005	Harumi Minekawa	Q91103	7981

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WASHINGTON, DC 20037

EXAMINER
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BABIC, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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11/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/561,947	Applicant(s) MINEKAWA ET AL.	
	Examiner Christopher M. Babic	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5, 7, 12 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 12 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Claims*

Claim(s) 5, 7, 12, and 21 are pending. The following Office Action is in response to Applicant's response dated September 18, 2007.

### ***New Grounds Claim Rejections - 35 USC § 112 - Indefiniteness***

The following new grounds of rejection is made in view of Applicant's amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim(s) 5, 7, 12, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

(a) The claimed invention is rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the active method step of detection, i.e. the step amplification does not inherently include a detection step. The lack of an active detection step amounts to a lack of nexus between the preamble, or intended goal, of the active method step of the claimed invention.

(b) Claim 12 recites the limitations --the F3c, the F2c, and the F1c region-- and --the R3, the R2, and the R1 region-- in the first paragraph. There is insufficient antecedent basis for this limitation in the claim.

***New Grounds Claim Rejections - 35 USC § 112 - New Matter***

The following new grounds of rejection is made in view of Applicant's amendments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Claim Rejections - 35 USC § 112 - New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claim(s) 5, 7, 12, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the limitation reciting, --an oligonucleotide primer comprising at least 15 contiguous nucleotides of SEQ ID NO: 17, 18, 19-- added in Applicant's response dated September 18, 2007, was not contemplated in the disclosure at the time the application was filed, and thus, is new matter.

Applicant points to claim(s) 2 and paragraph 32 of the published application as providing support for this amendment, however, these portions are not considered to explicitly or inherently provide support for the above amendment because claim(s) 2 recites an oligonucleotide primer comprising at least 15 contiguous nucleotides selected from the nucleotide sequences as shown in SEQ ID NOs: 2-13. Furthermore, paragraph 2 recites only that the primers of the claimed invention comprise preferably 15 nucleotides, rather than reciting that the primers comprise 15 contiguous nucleotides from explicit nucleotide sequences, such as SEQ ID NOs 17-19. Thus, a skilled artisan would recognize that primers of 15 nucleotides in length could be used within the claimed invention; however, a skilled artisan would not necessarily recognize that primers of 15 contiguous nucleotides of explicit sequences would be functional within the claimed invention because nowhere does the specification teach that the entire nucleotide sequences according to SEQ ID NOs: 17-19 are not necessary.

***New Grounds Claim Rejections - 35 USC § 112 - Written Description***

The following new grounds of rejection is made in view of Applicant's amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found above.

**Claim(s) 5, 7, 12, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement ensures that an applicant invented the subject matter that is claimed. Further, the written description requirement for a claimed genus may be satisfied through a sufficient description of a representative number of species by 1) reduction to practice; 2) reduction to drawing; or 3) disclosure of relevant identifying characteristics (i.e., structure of other physical and/or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure) (see MPEP 2136).

In the instant case, the claimed invention encompasses oligonucleotide sequences that are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the species. Specifically, the claimed invention encompasses, for example, nucleotide sequences complementary to a sequence of at

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least 15 contiguous nucleotides of SEQ ID NO: 17, e.g. a 6-mer, 7-mer, 8-mer. etc. In other words, the claimed invention does not require a length (e.g. **full complement thereof**) of the --complementary-- oligonucleotides.

Reduction to Practice

The specification does not include experimentation with a --complementary-- oligonucleotide of the claimed invention.

Reduction to Drawing

The specification does not provide a SEQ ID NOs reciting a --complementary-- oligonucleotide of the claimed invention.

Disclosure of Relevant Identifying Characteristics

Applicant has not disclosed enough number of species within the claimed genus that would indicate a characteristic primer sequence within the 15 contiguous nucleotides that would permit a person skilled in the art to clearly recognize that Applicant had possession of the genus embraced by the claimed invention. In other words, Applicant has not demonstrated a required nucleotide sequence within the 15 contiguous nucleotides that would indicate a required complementary oligonucleotide sequence.

Thus, for the foregoing reasons, the genus embraced by the claims is not sufficiently described by the number of species disclosed in the specification, and therefore, the specification lacks written description of the claims.

### ***Prior Art Search***

A search of the appropriate sequence databases and relevant textual art revealed no prior art teaching or suggesting an amplification method that requires the four SEQ ID NO based primers of the claimed invention.

### ***Conclusion***

**Claim(s) 5, 7, 12, and 21 are rejected. No claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

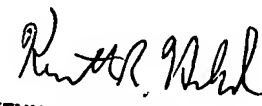
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



11/6/07

Christopher M. Babic  
Patent Examiner

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

11/8/07